Remarks

Claims 1-38 were previously pending in the subject application. By this amendment, the applicants have cancelled claims 1-38 and added new claims 39-62. The abstract of the Disclosure has been amended and also the specification has been amended to correct minor errors. No new subject matter has been added by these amendments. Accordingly, claims 39-62 are now before the Examiner for consideration.

Claims have been cancelled and new claims added herein in order to expedite prosecution by simplifying and reducing the number of issues for consideration. The applicants have also endeavored to lend greater clarity to the claimed subject matter. Accordingly, the amendments set forth herein should not be interpreted to indicate that the applicants have agreed with, or acquiesced to, the rejections set forth in the outstanding Office Action. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Ventilation is the process of delivering oxygen to, and washing carbon dioxide from, the lungs. When receiving ventilatory support, a patient becomes part of a complex system that must provide adequate ventilation and promote appropriate gas exchange to aid in the stabilization and recovery of the patient. Clinical treatment of a ventilated patient often calls for monitoring the patient's breathing to detect an interruption or an irregularity in the breathing pattern, for triggering a ventilator to initiate assisted breathing, and/or for interrupting the assisted breathing periodically to wean the patient off of the assisted breathing regime, thereby restoring the patient's ability to breath independently.

The present invention advantageously provides a ventilation monitoring system that employs an intelligence system that monitors and evaluates the system's performance as it relates to a particular patient in order to tailor the supply of breathing gas to meet the specific needs of the individual patient at any given time. This system can be used to automatically adjust the ventilator, or to recommend to a physician appropriate ventilator control settings in order to optimize treatment.

Prior microprocessor-controlled ventilators suffer from compromised accuracy because complicated algorithms were used to "approximate" what was actually occurring within the patient's

lungs. The usefulness of such ventilators is constrained due to the inflexible nature of the mathematical algorithms that attempt to mimic cause and effect in the ventilator.

Unfortunately, as ventilators become more complicated and offer more otions, the number of potentially dangerous clinical decisions increases. Physicians, nurses, and respiratory therapists that care for the critically ill are faced with expensive, complicated machines with few clear guidelines for their effective use. The setting, monitoring, and interpretation of some ventilatory parameters has become more speculative and empirical, leading to potentially hazardous misuse of these new ventilators

Advantageously, the subject invention provides a unique ventilation monitoring system that can accurately provide specific, tailored recommendations for ventilator settings that meet the physiological ventilation support needs of a particular patient.

Initially, the drawings have been objected to under 37 CFR 1.83(a) and 37 CFR 1.84(p)(4). The Office Action indicates that certain reference characters indicate the same structural element. In addition, reference character 52 designates one sensor and a plurality of sensors. The applicants respectfully submit that reference characters 30, 32, 34, and 36 are pointing to separate structural elements. By this amendment, Figure 3 has been revised to remove references to character 52. Formal Figures 1-8 and a marked-up version of Figure 3 are attached for the Examiner's review. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

The abstract has been objected to for language and format. By this amendment, the applicants have submitted an amended abstract to address the objection.

Claims 19-38 have been rejected under 35 U.S.C. §112, second paragraph as being indefinite. In order to expedite prosecution, claims 1-38 have been cancelled and new claims 39-61 have been added herein to provide antecedent basis for certain limitations recited in the claims and to address the various issues raised by the Examiner. The applicants appreciate the Examiner's careful review of the claims and believe that the issues raised by the Examiner have been addressed as a result of the claim cancellations and amendments as set forth herein. Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 1-38 have been rejected under 35 U.S.C. §102(b) as being anticipated by Biondi *et al.* (U.S. Patent No. 6,158,432). To the extent that this rejection might be applied to the new claims presented herein, the applicants respectfully traverse this grounds of rejection because the Biondi *et al.* reference does not teach or suggest the applicants' unique system for ventilation monitoring.

Although the Biondi *et al.* system and the system of the current invention share certain superficial similarities, a careful comparison of the systems reveals critical differences. Please note that the applicants have endeavored to amend their claims in order to add greater clarity such that the critical distinct attributes of the current invention are more readily apparent.

Unlike the Biondi *et al.* system the system of the subject invention is particularly advantageous because of its ability to evaluate the system's performance, in the context of a particular patient at a particular time, and recommend optimal ventilator control settings. It is important to recognize that, when the current applicants refer to "ventilation control settings" they are referring to the settings that have traditionally been entered by a physician based upon, for example, judgment, instinct, and experience with other patients.

The Biondi *et al.* system operates quite differently from the claimed invetnion. The Biondi *et al.* system requires the physician to select (based on, for example, judgment, instinct, and past experience) specific ventilator control settings. The Biondi *et al.* system then monitors the performance of the system and, based on simulator algorithms, adjusts the mechanics of the system to effect the directions that were selected by the physician. The Biondi *et al.* system does not and cannot recommend appropriate settings to best facilitate patient care. Rather, the Biondi *et al.* system simply tries to carry out the operator's instructions.

The simulator disclosed by Biondi *et al.* applies predetermined data structures with predetermined computational instructions to monitor patient ventilation (see for example, col. 13, line 57 through col. 14, line 62). By comparison, the current invention does not deliver instructions based on predetermined data structures to monitor patient ventilation. Rather, the current invention utilizes intelligence-based technology to evaluate both patient status and ventilator settings in generating individual recommended ventilator control settings.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

> Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

In *Dewey & Almy Chem. Co. v. Mimex Co.*, Judge Learned Hand wrote:

> No doctrine of the patent law is better established than that a prior patent . . . to be an anticipation must bear within its four corners adequate directions for the practice [of the subsequent invention] . . . if the earlier disclosure offers no more than a starting point . . . if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. 124 F.2d 986, 990; 52 USPQ 138 (2nd Cir. 1942).

The current applicants respectfully submit that Biondi *et al.* do not disclose the currently-claimed method and system wherein an intelligence system evaluates output signals and ventilator parameter signals to recommend ventilator control settings. Because Biondi *et al.* do not disclose such a system, the applicants' claims cannot be said to be anticipated by Biondi *et al.*

Additionally, as noted above the distinctions between the current invention and the Biondi *et al.* system are not trivial. In fact, it is precisely the differences between the current invention and Biondi *et al.* that make the current invention particularly advantageous. The Biondi *et al.* system only uses rigid algorithms to try to control the ventilator in order to effect settings entered by the operator. Thus, the care of the patient still depends entirely on judgments made by the operator. In contrast, the subject invention provides a system whereby a multiplicity of variables can be monitored in order to assess the need of a particular patient. These variables, which can include various measures of the patient's physiological response to the ventilator can then be used to achieve the appropriate

therapeutic goal. By carefully monitoring the patient in this way, it is now possible to improve and expedite recovery. This is, of course, a tremendous benefit to the patient, the caregiver and the hospital. Such an advantageous system is neither disclosed nor suggested by Biondi *et al.* Accordingly, the applicants respectfully request reconsideration and withdrawal of the prior art rejection based on Biondi *et al.*

Claims 1-38 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of U.S. Patent application Serial No. 09/607,713 (hereinafter the '713 application). The applicants are planning on abandoning the '713 application upon an indication of allowable claims in the subject application.

In view of the foregoing remarks and amendment, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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DRS/la
Attachment: Marked-up version of substituted specification and abstract
New formal drawings

Marked-up Version of Substituted Abstract

Paragraph at page 45, first paragraph (lines 1-15):

[Embodiments of the present invention described and shown in the specification and drawings include]The present invention provides a[n] system and method for monitoring the ventilation support provided by a ventilator that is supplying a breathing gas to a patient via a breathing circuit that is in fluid communication with the lungs of the patient. The ventilator has a plurality of selectable ventilator setting controls governing the supply of ventilation support from the ventilator, each setting control selectable to a level setting. The ventilator support monitor system preferably receives at least one ventilator setting parameter signal, each ventilator setting parameter signal indicative of the level settings of one ventilator setting control, monitors a plurality of sensors, each sensor producing an output signal indicative of a measured ventilation support parameter, to determine the sufficiency of the ventilation support received by the patient, and determines the desired level settings of the ventilator setting controls in response to the received ventilator setting parameter signal and the output signals. The ventilator support monitor system preferably utilizes a trainable neural network to determine the desired level settings of the ventilator setting controls.[It is emphasized that this abstract is provided to comply with the rules requiring an abstract which will allow a searcher or other reader to quickly ascertain the subject matter of the technical disclosure. It is submitted with the understanding that is will not be used to interpret or limit the scope or meaning of the claims. 37 C.F.R. § 1.72(b).]

Marked-up Version of Substituted Specification

Paragraph starting at page 12, lines 33 through page 13, line 23:

In one preferred embodiment shown in Fig. 3, the processing subsystem 30 is shown operatively connected to a plurality of sensors such as a flow rate sensor 53, [a] an exhaled CO2 (ex CO2) sensor 54, a pressure sensor 55, a blood pressure sensor 56, and a SPO2 sensor 57. In this embodiment, it is preferred that the monitor system 10 be responsive to the output signals 51 input into the processing subsystem 40 from, for example: i) the flow rate sensor 53 which is indicative of the flow rate ventilation support parameter of the gas expired/inspired by the patient P within the breathing circuit 22, ii) the gas pressure sensor 55 which is indicative of the pressure ventilation support parameter of the breathing gas within the breathing circuit 22, and iii) the Ex CO2 sensor 54 which is indicative of the exhaled carbon dioxide ventilation support parameter present in the exhaled gas expired by the patient P within the breathing circuit 22 (*i.e.*, the flow rate output signal 51 generated by the flow rate sensor 53, the gas pressure output signal 51 generated by the gas pressure sensor 55, and the Ex CO2 output signal 51 generated by the Ex CO2 sensor 54). Optionally, the monitor system 10 may be responsive to output signals 51 input into the processing subsystem 40 from the output of the blood pressure sensor 56, which [in] is indicative of the blood pressure ventilation support parameter of the patient P, for example the arterial systolic, diastolic, and mean blood pressure of the patient P, and the SPO2 sensor 57 which is indicative of the hemoglobin oxygen saturation level ventilation support parameter of the patient P (*i.e.*, the blood pressure output signal 51 generated by the blood pressure sensor 56 and the SPO2 output signal 51 generated by the SPO2 sensor 57).

Paragraph starting at page 13, line 25 through page 14, line 9:

The flow rate sensor 53, the pressure sensor 55, and the Ex CO2 sensor 54 are preferably positioned between the patient connector 26 and the patient connection tube 25. Alternatively, it is preferred that the pressure sensor 55 be located at the tracheal end of the patient connection tube 25. The flow rate, pressure, and Ex CO2 sensors 53, 55, 54 are exemplified by Novametrics, CO_2SMO+

monitor (which has [a] flow rate, pressure, and ExCO2 sensors). The blood pressure sensor 56 and the SPO2 sensor 57 are exemplified by Dynamap, Inc.'s blood pressure sensor and Novametrics, CO_2SMO+ monitor's SPO2 sensor. The blood pressure sensor 56 and the SPO2 sensor 57 may be attaché dot a portion of the patient's body to render the requisite measurements. For example, the blood pressure sensor 56, here for example shown as a blood pressure cuff, is shown attached to the arm of the patient P and the SPO2 sensor 57, which may, for example, be a pulse oximeter, is shown attached to a finger of the patient_12. One skilled in the art will appreciate[,] the blood pressure data may be derived form the SPO2 sensor 57 which eliminates the need for the blood pressure sensor 56.